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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/198,018	11/23/1998	THOMAS W. ASTLE	130-125	1987

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EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

14

DATE MAILED: 10/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

myk-14

Office Action Summary

Application No.

09/198,018

Applicant(s)

ASTLE, THOMAS W.

Examiner

P. Kathryn Bex

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 19, 20 and 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 21-23 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9, now recites the removal of the sealing material after adhesion to the carrier tape “by pulling the sealing material from said carrier tape without the use of a knife structure.” The instant specification does not exclude the use of a “knife structure”. Applicant is reminded that the addition of a negative limitation to carve out subject matter discovered in the prior art violates the description requirement of 35 USC 112 on the basis of lack of enablement and lack of description. The negative limitation recited in claim(s), did not appear in specification or claims as originally filed and therefore introduce new concepts into the disclosure, see *Ex parte Grasselli, et al*, 231 USPQ 393 (BdPatApp&Int 1983). Same deficiency was found in claim 10.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 9, last line, recites the use of the word "knife structure." It is unclear what distinguishes a heated "knife" structure from a heated "roll" structure. Moreover, since the specification fails to clarify the subject matter, it is not possible to clearly define the metes and bounds of the invention as claimed. Same deficiency was found in claim 10.

Claim 15, paragraph a) recites "said holes being disposed near upper edges of said chemical receiving wells." The term "near" is a relative term which renders the claim indefinite. The term "near" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It not clear what Applicant considers how "near" the holes are disposed in relation to the upper edges of the chemical receiving wells.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 21-22 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Guigan (USP 3,620,678).

Guigan anticipates the instant claims by teaching a method of chemical compound storage comprising providing a longitudinally extending carrier tape 1,12 having two or more matrices of thermoformed chemical receiving wells 3, 13, 30, 31,168 and simultaneously adding to each of the chemical receiving wells a chemical compound via needles 47 and 49 (column 5, line 48-57, Fig. 9). Note: Guigan clearly teaches the use a thermoplastic material (column 4, line

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34) and heat and pressure to form the wells (column 9, lines 23-30, Fig 1-3, and 9). Guigan teaches a liquid tight sealing material 10 placed over the chemical receiving wells (column 3, lines 18-43, Fig. 3 and Fig. 18). Additionally, the sealing material being heat sealed to the carrier tape is taught at col. 4, lines 30-38. The tractor drive 150 for indexing repetitive patterns of wells is taught at Fig. 20. The “matrix” of Guigan is a “N X 1” matrix with an rectangular arrangement of wells with N rows and 1 column along the carrier tape.

7. Claims 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Howell (USP 4,863,693).

Howell anticipates the instant claims by teaching a device for chemical compound storage comprising providing a longitudinally extending carrier tape 46 having a plurality of thermoformed chemical receiving wells 96, wherein the wells being disposed in two or more matrices on the carrier tape. The chemical added to each of the chemical receiving wells a chemical compound via pipette 116. Howell teaches the use a thermoplastic material (column 4, line 46-47) and heat and pressure to form the wells (column 3, line 30- column 4, line 15, Fig. 1). Moreover, Howell teaches a liquid tight sealing material 56 placed over the chemical receiving wells in which a closure device 115 may be mounted to a plate to completely seal the well 96 (column 5, lines 35-39, Fig. 1). Wherein the sealing material is heat sealed to the carrier tape (column 2, lines 8-10). The tractor drive 112 for indexing repetitive patterns of wells. Note: a matrix is accepted with in the art to mean a rectangular arrangement into rows and columns. The “matrix” of Howell is a “N X 1” matrix with an rectangular arrangement of wells with N rows and 1 column along the carrier tape.

Claim Rejections - 35 USC § 103

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8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 3-8, 16-18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) in view of Anderson (USP 5,092,466).

Guigan as discussed previously, do not disclose repetitive matrices with a unique identifier. However, such an identifier is considered conventional in the art, see Anderson. Anderson teaches an apparatus and method for storing samples in sealed packets 14 on a carrier strip 32. Additionally, Anderson teaches a die cutting the sealing material around the wells (column 3, lines 5-13). Anderson also disclose the step of cutting out segment along perforations of the carrier tape with attached sample (column 5, lines 7-22). Moreover, Anderson teaches repetitive matrix with a unique identifier 22, 24 (Fig. 1).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the chemical storage apparatus of Guigan with the

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identification means of Anderson, in order to reduce the costs of storage, inventory management, and distribution of a very large number of biological samples (col. 2, lines 17-23).

Regarding the specific material of the carrier tape, it would have been obvious to one of ordinary skill in the art to have made the carrier tape of Guigan with the polycarbonate, polystyrene or polypropylene, in order to ensure that the carrier tape is chemically inert with respect to the substances being stored. Since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With respect to the number of chemical receiving wells in repetitive matrixes selected from the group consisting of 8 by 12 with a spacing of 9 mm between centers and the specific dimensions of the carrier tape, etc. It would have been an obvious matter of design choice to have made the chemical receiving wells in repetitive matrixes selected from the group consisting of 8 by 12 with a spacing of 9 mm between centers of Anderson in order to increase amount of samples which are assayed. Further, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

11. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howell (USP 4,863,693).

Howell as discussed previously, does not disclose the formation of the carrier tape into a compact roll having about 100,000 aliquots and dimensions of about 16 in. in diameter and 4 in. wide. With respect to the number of chemical receiving wells in a roll and the specific dimensions of the roll of carrier tape, etc. It would have been an obvious matter of design choice

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to one of ordinary skill in the art at the time of the claimed invention to have made a roll of Howell having about 100,000 aliquots and dimensions of about 16 in. in diameter and 4 in. wide, in order to increase amount of samples which are assayed. Further, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

12. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) in view of Hansen *et al* (USP 4,565,783).

Guigan does not teach the sealing material with a pressure sensitive adhesive to adhere the sealing material to the carrier tape such as to permit removal of the sealing material after adhesion to the carrier tape. Hansen *et al* do teach the sealing material with a pressure sensitive adhesive to adhere the sealing material to the carrier tape such as to permit manual removal of the sealing material after adhesion to the carrier tape without the use of a knife structure (col. 3, lines 58-68, col. 8, lines 24-56). The lower seal layer having a low melting point (polyethylene) and upper high melting point layer (polyester) joined to the seal layer is taught by Hansen *et al* col. 8, lines 24-34. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided in the chemical storage apparatus of Guigan, the pressure sensitive adhesive as taught by Hansen *et al* in order to prevent contamination of the device during storage and incubation (col. 2, lines 19-22).

13. Claims 9-13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) in view of Tidemann *et al* (USP 5,526,935).

Guigan does teach holes 5 perforating the carrier tape between the chemical receiving wells near the upper edges of the wells (column 4, lines 56-57, Fig. 1). Guigan fail to teach the step of evacuating space between the seal material and the carrier tape at the time of sealing. Tidemann *et al* teach a polycarbonate carrier tape 100, 102 comprising a multi-layer sealing material 120 placed in a liquid tight seal to form a well 112. The sealing material made of polyester (column 4, line 12) and having a layer formed of ethyl vinyl acetate (column 6, line 24). Moreover, Tidemann *et al* do teach the use of an aperture 118 to apply a vacuum to the well which evacuates the space between the seal material 120 and the carrier tape 102. (column 5, line 29-30, Fig. 2). Such a step of evacuation allows for more efficient loading of the wells with components (column 5, lines 29-30). Additionally, Tidemann *et al* do teach the sealing material with a pressure sensitive adhesive or heat-sealing means to adhere the sealing material to the carrier tape such as to permit removal of the sealing material after adhesion to the carrier tape.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method of Guigan with the step to evacuate the space between the seal material and the carrier tape, as taught by Tidemann *et al* in order to allow for more efficient loading of the wells with components.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) in view of Paquette (USP 4,159,953).

Guigan does not teach the step of removing the seal material from the carrier tape by using a heated roll. Paquette does teach a filter plate with bores 28, in which a sealing material 25 is placed over. Additionally, Paquette do teach the step of removing the sealing material via

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a heated striper means 51 (column 5, lines 42-55, Fig. 3). Such a step of removing the sealing material provides for a readily reusable filter plate immediately following the removal of the seal material. Therefore there is no need to use a new filter plate (column 8, lines 10-23).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method of Guigan with the step to remove the seal material from the carrier tape, as taught by Paquette, in order to allow for more economical use of the carrier tape.

Response to Arguments

15. Applicant's arguments filed August 12, 2002 have been fully considered but they are not persuasive. In regard to the previous rejection of claims 1-3, 21-23 and 30 under 35 U.S.C. 102(b) as being anticipated by Guigan (USP 3,620,678), Applicant argues that Guigan does not teach wells which are thermally formed. Examiner points out that Applicant appears to believe the process of thermoforming is well-known in the art and therefore it is applicable that the specification of the prior art need not disclose what is so well known in the art, see page 3, 6th full paragraph of the Response. Additionally, the process of heat formation of the wells with a die taught by Guigan (column 9, lines 23-34). Therefore, the wells of Guigan have clearly been "thermally" formed by heat and pressure (column 4, lines 30-39).

Applicant argues that in Figure 1 of Guigan the openings 4 are left for access to the capsules and it must be "assumed" that similar openings are provided in the other embodiments. Examiner does not agree since the other embodiments disclose the use of chamber for transporting reagents in a liquid form, therefore necessitating that the wells are provided with a liquid-tight seal (column 3, lines 40-43, column 5, lines 5-20).

With respect to the previous 35 U.S.C. 102(b) rejection under Howel (USP 4,863,693), Examiner notes that Applicant's arguments do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. This is also applicable to the previous rejection of claims 9-13 under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) or Howel (USP 4,863,693), in view of Hansen *et al* (USP 4,565,783).

With respect to the previous rejection of claims 9-13, 15 under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) in view of Tidemann *et al* (USP 5,526,935), Applicant argues that Tidemann *et al* only adheres the cover to the edges of the carrier. This argument is not germane to the issue since Applicant has not restricted the location of sealing the cover to the carrier. Additionally, Applicant argues that Tidemann *et al* do not teach removing the cover by heating. Examiner points out this recitation is claim 14, which was rejected under Paquette (USP 4,159,953).

With respect to the previous rejection of claim 14 under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) in view of Paquette (USP 4,159,953), Applicant argues that Paquette uses a knife structure to strip a cover from a slide plate filter. Again, this argument is not germane to the issue since Applicant has not excluded the use of knife structure in claim 14. This limitation was included in claims 9 and 10, however claim 14 depends from claim 2.

Conclusion

16. No claims allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
October 22, 2002

Jill Warden
Jill Warden
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